K092867

510(K) Summary

OCT - 1 2009

A. Submitter Information

Submitter's Name:	Kettenbach GmbH & Co. KG
Address:	Im Heerfeld 7 D-35713 Eschenburg, Germany
Phone Number:	(+49) 2774-705-58
Fax Number:	(+49) 2774-705-33
Contact Person:	Michaela Zinke
Date of Preparation:	July 24, 2009

B. Device Name

Trade Name:	*Identium® Impression Materials*, to include: ▪ *Identium® Heavy* ▪ *Identium® Medium* ▪ *Identium® Medium soft* ▪ *Identium® Light*
Common/Usual Name:	Impression Material
Classification Name:	Material, Impression (21 CFR 872.3660, Product Code: ELW)

C. Predicate Devices

Trade Name:	Panasil® Impression Materials (K082560, K083701)
Trade Names:	GC Fusion/SENN and Fusion Fast Set/SENN Impression Materials (K041398, K043471)

D. Device Description

Identium® Impression Materials are addition-curing, elastomeric materials. *Identium® Impression Materials* have excellent flow and hydrophilic properties, high tear strength, dimensional accuracy, and resistance to permanent deformation. The *Identium® Impression Materials* family consists of three different viscosities (heavy-bodied, medium-bodied, light-bodied). They are available in two delivery systems, for use in most automatic dispensing and

mixing systems: standard 1:1 (50 ml automix cartridges) and 5:1 (362 ml foil bags). The *Identium® Impression Materials* are available in regular-set and fast-set versions.

E. Intended Use

The *Identium® Impression Materials* are intended to:

- be placed on an impression tray (or injected directly into the mouth, depending on the technique and device) and used to reproduce the structure of a patient's teeth and gums;
- provide models for study and for production of restorative prosthetic devices.

F. Indications for Use

Identium Heavy is to be used as a heavy-bodied impression material in one-step technique (double mix) for:

- Impressions for crowns/bridges, inlays/onlays and veneer preparations
- Functional impressions
- Impressions for full or partial dentures
- Implant impressions

Identium Medium is to be used as a medium-bodied tray or syringeable impression material in one-step technique (monophase or double mix) for:

- Impressions for crowns/bridges, inlays/onlays and veneer preparations
- Implant impressions
- Fixation impressions
- Functional impressions

Identium Medium soft is to be used as a medium-bodied tray or syringeable impression material in one-step technique (monophase or double mix) for:

- Impressions for crowns/bridges, inlays/onlays and veneer preparations
- Functional impressions
- Reline impressions

Identium Light is to be used as a light-bodied, syringeable impression material in one-step technique (double mix) for:

- Impressions for crowns/ bridges, inlays/ onlays and veneer preparations
- Reline impressions
- Impressions for full or partial dentures

G. Technological Characteristics Summary

The technological characteristics of *Identium® Impression Materials* are substantially equivalent to the predicate device technological characteristics. *Identium® Impression Materials* and the predicate devices are addition-curing, elastomeric materials, designed and manufactured for use as dental impression materials.

H. Performance Data

No performance standards have been established for this type of device. *Identium® Impression Materials* have been evaluated in accordance with the applicable criteria established in *Guidance for Industry and FDA Staff: Dental Impression Materials – Premarket Notification (Doc#2203, 8/17/1998)* and *ISO 4823 (Dentistry – Elastomeric impression materials):2000/Cor 1:2004/Amd 1:2007*. The results of device performance testing demonstrated that *Identium® Impression Materials* are suitable for use as dental impression materials. *Identium® Impression Materials* have been designed and manufactured to perform in a manner substantially equivalent to that of the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

OCT - 1 2009

TÜV SÜD America, Incorporated
C/O Mr. Stefan Preiss
Responsible Third Party Official
Kettenbach GmbH & Company KG
1775 Old High Way 8 NW, Suite 104
New Brighton, Minnesota 55112-1891

Re: K092867
Trade/Device Name: Identium® Light, Identium® Medium Soft, Identium® Medium, Identium® Heavy
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: II
Product Code: ELW
Dated: September 16, 2009
Received: September 18, 2009

Dear Mr. Preiss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092867

Device Name: *Identium® Light*

Indications for Use:

***Identium Light* is to be used as a light-bodied, syringeable impression material in one-step technique (double mix) for:**

- Impressions for crowns/bridges, inlays/onlays and veneer preparations
- Reline impressions
- Impressions for full or partial dentures

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K092867

Indications for Use

510(k) Number (if known): K092867

Device Name: *Identium® Medium soft*

Indications for Use:

***Identium Medium soft* is to be used as a medium-bodied tray or syringeable impression material in one-step technique (monophase or double mix) for:**

- Impressions for crowns/bridges, inlays/onlays and veneer preparations
- Functional impressions
- Reline impressions

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 3 of 4

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

Indications for Use

510(k) Number (if known): K092867

Device Name: *Identium® Medium*

Indications for Use:

***Identium Medium* is to be used as a medium-bodied tray or syringeable impression material in one-step technique (monophase or double mix) for:**

- Impressions for crowns/bridges, inlays/onlays and veneer preparations
- Implant impressions
- Fixation impressions
- Functional impressions

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

Kettenbach GmbH & Co. KG

510(k) Number: K092867

Indications for Use

510(k) Number (if known): K092867

Device Name: *Identium® Heavy*

Indications for Use:

***Identium Heavy* is to be used as a heavy-bodied impression material in one-step technique (double mix) for:**

- Impressions for crowns/bridges, inlays/onlays and veneer preparations
- Functional impressions
- Impressions for full or partial dentures
- Implant impressions

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Kai Mulay for MSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

Kettenbach GmbH & Co. KG

510(k) Number: K092867